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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,778	09/27/2005	Jurg Zumbrunn	753-54 PCT/US	1788

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EXAMINER
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NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1654

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03/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,778	<b>Applicant(s)</b> ZUMBRUNN ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 40-70 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

Claims 1-39 have been cancelled. Claims 40-70 are under consideration.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a three membered ring with nitrogen as in A1.

Group 2, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a four membered ring with nitrogen as in A2-A4,A76.

Group 3, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a five membered ring with nitrogen as in A5-A11,A79,A82-A83.

Group 4, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a five membered ring with nitrogen attached to a six membered ring as in A12-A14,A89,A92,A97.

Group 5, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a six membered ring with nitrogen as in A15-A18,A20-A28,A89.

Group 6, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes two or more six membered rings as in A19,A29-A37,A100-101,104.

Group 7, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a seven membered ring with nitrogen as in A38-A57.

Group 8, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 9, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes linear residues as in A70-A72.

Group 10, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a three membered ring with no nitrogen in the ring as in A73.

Group 11, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a four membered ring with no nitrogen in the ring as in A74-A75.

Group 12, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a five membered ring with no nitrogen in the ring as in A77-A78,A80-A81.

Group 13, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a five membered ring with no nitrogen in the ring and another six membered ring as in AA84-A86.

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Group 14, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a six membered ring with no nitrogen in the ring as in A87-A88,A90-91,A93-96.

Group 15, claim(s) 40-64 in part, drawn to compounds/compositions wherein A includes a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99,A102-103.

Group 16, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a three membered ring with nitrogen as in A1.

Group 17, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a four membered ring with nitrogen as in A2-A4,A76.

Group 18, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a five membered ring with nitrogen as in A5-A11,A79,A82-A83.

Group 19, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a five membered ring with nitrogen attached to a six membered ring as in A12-A14,A89,A92,A97.

Group 20, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a six membered ring with nitrogen as in A15-A18,A20-A28,A89.

Group 21, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes two or more six membered rings as in A19,A29-A37,A100-101,104.

Group 22, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a seven membered ring with nitrogen as in A38-A57.

Group 23, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 24, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes linear residues as in A70-A72.

Group 25, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a three membered ring with no nitrogen in the ring as in A73.

Group 26, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a four membered ring with no nitrogen in the ring as in A74-A75.

Group 27, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a five membered ring with no nitrogen in the ring as in A77-A78,A80-A81.

Group 28, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a five membered ring with no nitrogen in the ring and another six membered ring as in AA84-A86.

Group 29, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a six membered ring with no nitrogen in the ring as in A87-A88,A90-91,A93-96.

Group 30, claim(s) 65 in part, drawn to methods of treating/preventing using a compound wherein A includes a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99,A102-103.

Group 31, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a three membered ring with nitrogen as in A1.

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Group 32, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a four membered ring with nitrogen as in A2-A4,A76.

Group 33, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a five membered ring with nitrogen as in A5-A11,A79,A82-A83.

Group 34, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a five membered ring with nitrogen attached to a six membered ring as in A12-A14,A89,A92,A97.

Group 35, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a six membered ring with nitrogen as in A15-A18,A20-A28,A89.

Group 36, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes two or more six membered rings as in A19,A29-A37,A100-101,104.

Group 37, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a seven membered ring with nitrogen as in A38-A57.

Group 38, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 39, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes linear residues as in A70-A72.

Group 40, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a three membered ring with no nitrogen in the ring as in A73.

Group 41, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a four membered ring with no nitrogen in the ring as in A74-A75.

Group 42, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a five membered ring with no nitrogen in the ring as in A77-A78,A80-A81.

Group 43, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a five membered ring with no nitrogen in the ring and another six membered ring as in A84-A86.

Group 44, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a six membered ring with no nitrogen in the ring as in A87-A88,A90-91,A93-96.

Group 45, claim(s) 66-70 in part, drawn to methods of making a compound wherein A includes a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99,A102-103.

The inventions listed as Groups 1-45 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 defines “special technical features” as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” Claim 40 is drawn to a compound of a general formula. The STN database (STN database entry for registry number 493552-90-2 entered Feb

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21 2003 2 pages) teach that registry number 493552-90-2 is a protein from a mouse. Residues 691-702 of the protein are Pro-Arg-Ser-Cys-Tyr-Ile-Thr-Pro-Lys-Arg-Pro-Arg. The instant invention includes an embodiment which is P6'-P5'-P4'-P3'-P2'-P1'-B-A-P1-P2-P3-P4. Page 31 of the claims and claim 50 set forth examples of the possible residues. Page 31 states that P6' can be Pro (compare residue 691 of registry number 493552-90-2); claim 50 states that P5' is Arg (compare residue 692 of registry number 493552-90-2); page 31 states that P4' can be type C which includes (see page 27 of claims) R72 being  $-(CH_2)_p(CHR_{61})_sOR_{85}$ , when p is 1, s is 0 R85 is lower alkyl which is defined (see section 0150 of PGPUB) to be a radical which can be hydrogen P4' can be Ser (compare residue 693 of registry number 493552-90-2); claim 50 states that P3' can be Cys (compare residue 694 of registry number 493552-90-2); claim 50 states that P2' can be Tyr (compare residue 695 of registry number 493552-90-2); page 31 of the claims states that P1' can be of type C which includes R72 lower alkyl such as Ile (compare residue 696 of registry number 493552-90-2); page 8 states that B can be Thr (compare residue 697 of registry number 493552-90-2); page 4 shows that A can be Pro (compare residue 698 of registry number 493552-90-2); claim 51 states that a particular residue (P1') is Lys thus D,E,F (see claim 49) must include Lys so P1 as recited on page 31 must include Lys (compare residue 699 of registry number 493552-90-2); claim 50 shows that P2 can be Arg (compare residue 700 of registry number 493552-90-2); page 31 states that P3 can be Pro (compare residue 701 of registry number 493552-90-2); claim 50 shows that P4 can be Arg (compare residue 702 of registry number 493552-90-2). Thus the peptide of the prior art is of the general formula of the peptide of the instant invention. Thus the technical features are not a contribution over the prior art and the claims lack unity.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Election of Species*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For whichever group is elected, species election is necessary for:

**Compound:** a specific compound should be identified such that all variable groups are uniquely defined. For example, applicant could identify a specific sequence as set forth in one of the tables.

Further, if applicant elects any of Groups 16-30 a species election is necessary for:

**Patient population:** a specific patient population should be identified from those recited in claim 65. It is noted that if applicant elects 'inflammatory disorders' they should specify a specific embodiment of an inflammatory disorder.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to at least one of the species.

There is an examination and search burden for the species due to their mutually exclusive characteristics. Each of the species are structurally distinct and one of skill in the art would not recognize that every alternative would behave in the same way. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.



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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper

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restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654